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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,963	02/11/2002	Philip Rodney Kwok	P 290534	2378

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EXAMINER	
EREZO, DARWIN P	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/068,963	KWOK ET AL.
	Examiner	Art Unit
	Darwin P. Erezo	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-99* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-99* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2,10*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 23-31 are rejected under 35 U.S.C. 102(e) as being anticipated by US 5,647,357 to Barnett et al.

3. Barnett teaches a nasal mask cushion comprising a substantially triangularly-shaped frame **12** having a rim; a membrane **18** also of resilient material (the membrane is resilient because it maintains its shape) but being more flexible than the frame, and being of the same shape as the rim and fixed to and extending away from the frame so as to have an outer surface spaced from the rim (see Fig. 3), a portion of the outer surface forming a face contacting seal portion; and nose-receiving cavity bounded by the frame and the membrane (as seen in Fig. 1); wherein the face contacting seal portion is generally coterminus with respect to the rim and is resiliently deformable towards the rim in use of the cushion (as seen in Fig. 2); wherein the membrane and the rim each having co-located notch (as seen in Fig. 1); wherein the membrane is shaped to contact the wearer's nose, wherein the membrane and rim are saddle-shaped, and

wherein the seal portion contacts the sides and over the bridge of the nose, and between the base of the nose and the top lip (as see in Fig. 2); wherein the membrane is adapted to contact the wearer's face and wherein only a single seal is provided.

4. As to claim 32, Barnett teaches a nasal mask cushion comprising a generally triangularly-shaped frame **12**, the frame including an outer surface and a notch (see Fig. 2); a generally triangularly-shaped membrane **18** also of resilient material but being more flexible than the frame, the membrane including an aperture adapted to receive the wearer's nose, an outer surface including a seal forming portion adapted to deform and form a seal over a portion of the wearer's face when the mask is in use, an inner surface, an edge defining the perimeter of the aperture, and a notch adapted to receive the bridge of the wearer's nose, wherein the aperture of the frame is larger than the aperture of the membrane (as shown in Fig. 3); and the edge of the membrane is spaced a distance from the frame.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al.

7. Barnett is silent with regards to the frame and membrane being formed in a single piece. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the frame and membrane as single piece because it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

8. Claims 34-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. and in view of US 5,243,971 to Sullivan et al.

9. As to claims 34, 36 and 38, Barnett teaches a nasal mask cushion assembly comprising a generally triangularly-shaped frame **12**, the frame including a first side and a second side opposite the first side, an aperture extending from the first side to the second side, a rim on the second side, and a notch in the rim adapted to receive a user's nose (see Fig. 2); and a generally triangularly-shaped membrane **18** of resilient material, the membrane including an aperture adapted to receive the wearer's nose, an edge defining the perimeter of the aperture, a notch in a region adapted to receive the bridge of the wearer's nose, a first surface including a seal forming portion disposed around the perimeter of the aperture adapted to deform and form a seal over a portion of the wearer's face in a region between the base of the nose and the upper lip and around the sides and over the bridge of the wearer's nose when the mask is in use (see Fig. 2), a second surface opposite the first surface that surrounds and is spaced a first distance from the rim of the frame in at least the region adapted to receive the bridge of

the wearer's nose when the mask is in use, wherein the membrane is more flexible than the frame; and wherein the aperture of the frame is larger than the aperture of the membrane (as shown in Fig. 3); and the edge of the membrane is spaced a distance from the frame. Barnett is silent with regards to the frame having a first side adapted to contact a mask body.

Sullivan teaches a respiratory mask comprising a frame **34** having a first side adapted to contact a mask body **19** and a second side adapted to receive a cushion **13**.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the frame of Sullivan in the device of Barnett because it is more cost effective by allowing the user to replace the frame and the cushion without replacing the mask body. Furthermore, it has been held that constructing a formerly integral structure (the frame of Barnett includes a mask body) into various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

10. As to claims 35, 37 and 39, Barnett is silent with regards to the frame and membrane being formed in a single piece. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the frame and membrane as single piece because it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 U.S. 164 (1893).

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 23-39 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,357,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations set forth in Claims 23-39 of the instant application are also claimed in the patent, e.g., a nasal mask cushion comprising a generally triangularly-shaped frame having an aperture, the aperture defining the perimeter of the rim, and a notch; a generally triangularly-shaped membrane including a seal forming portion adapted to deform and form a seal over a portion of a user's face, wherein the membrane is more flexible than the frame; the aperture of the frame is larger than the aperture of the membrane; and wherein the frame and the membrane are formed in a single piece.

13. Claims 40-99 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No.

6,513,526. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations set forth in claims 40-99 of the instant application are also claimed in the patent, e.g., a cpap treatment apparatus comprising a flow generator, a gas delivery conduit, a full-face mask comprising a mask body; and a full-face cushion secured to the mask body, the body and cushion including a substantially triangularly-shaped first membrane having a molded inwardly curved rim; a second membrane having a second molded inwardly curved rim, the second membrane being more flexible than the first membrane.

Response to Arguments

14. Applicant's arguments filed 09/24/2003 have been fully considered but they are not persuasive.

15. As noted in the applicant's remarks, Barnett was inadvertently labeled as prior art under 102(b). However, the rejection under 102(e) still stands. Applicant argues that Barnett does not teach a "substantially triangularly shaped frame of resilient material". However, resilient is defined as "capable of withstanding shock without permanent deformation" (Merriam-Webster Online Dictionary). Therefore, the rigid body portion **12** of Barnett qualifies as a resilient frame because it is able to withstand shock without permanent deformation. Furthermore, the body portion **12** qualifies as the recited frame because it covers all the limitations set forth in the claim. It should also be noted that body portion **12** and seal **18** have a co-located notch as seen in Fig. 1.

16. As for the Double Patenting rejection, it should be noted that the rejected claims in the instant application are matched up with the claims from the patent and that each limitation in the instant application are taught in the patent. The claims are rejected under nonstatutory obviousness double patenting because the only difference between the claims in the instant application and the patent is how the functional language for each structure limitation is recited. However, each structural limitation rejected under double patenting is taught in the corresponding patent.

Conclusion

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe

WEILUN LO
SUPERVISORY PATENT EXAMINER
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